Before the
FEDERAL COMMUNICATIONS COMMISSION
Washington, D.C. 20554

In the Matter of	)	
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Amendment of Parts 22, 90 and 94 of the Commission's Rules to Permit Routine Use of Signal Boosters	)	WT Docket No. 95-[illegible]
	)	RM-8200
	)	
	)	

To: The Commission

COMMENTS OF
SPACELABS MEDICAL, INC.

SpaceLabs Medical, Inc. ("SpaceLabs"), hereby submits comments in response to the Notice of Proposed Rulemaking ("NPRM"), FCC 95-204, released in the above-captioned proceeding on June 22, 1995.

In general, SpaceLabs supports efforts by the Commission to increase the efficiency with which the various private radio services use the spectrum, and to minimize the regulatory burdens that attend such activities. The use of boosters in the manner proposed in the NPRM, to provide fill-in service for Part 90 licensees would, in the main, be consistent with those goals. However, the Commission's proposal, if adopted without significant modification, could threaten the viability of a substantial number of vital biomedical telemetry systems -- which operate at very low powers (i.e., under 5 mW) on the offset channels of the 450-470 MHz band -- in use in hospitals and other major healthcare institutions throughout the country.

I. SPACELAB'S INTEREST IN THE PROCEEDING.

Since the late 1960s, SpaceLabs has been designing and manufacturing wireless electrocardiogram ("ECG") monitoring systems, initially using technology developed by the company

while working with NASA on then-new biomedical telemetry systems for the manned spaceflight program.[1/] At present, SpaceLabs estimates that approximately one-half of the 200,000 low-power portable ECG monitors estimated to be in use in U.S. healthcare facilities today operate on the 450-470 MHz splinter channels. Thus, permitting the operation of new unlicensed transmitters -- with no notice to, or coordination with, co-channel or adjacent channel users -- could have a significant impact on the vital medical services presently provided by these telemetry systems.

II. OVERVIEW OF WIRELESS BIOMEDICAL TELEMETRY.

A. System Functions and Capabilities.

An ECG monitoring system records and visually displays the electrical currents that stimulate the contraction of the

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1/ Because of a variety of fairly inflexible power and weight considerations discussed infra, these systems must operate in the band between 100 and 1,000 MHz. SpaceLabs' early generations of ECG monitors (as well as those of other manufacturers) primarily operated in the VHF band, under the provisions of Part 15 of the Rules. See generally SpaceLabs, Inc., 26 F.C.C.2d 40 (1970); Laser Systems and Electronics, Inc., 26 F.C.C.2d 19 (1970). Eventually, the Commission established an exclusive reserve for biomedical telemetry operations under Part 15, on the vacant VHF television channels in the 174-216 MHz band. See 47 C.F.R. § 15.241; Biomedical Telemetry Radio Systems, 33 F.C.C.2d 880 (1972).

However, because of the severe restrictions on power levels inherent in Part 15 operations (i.e., a maximum field strength of 1500 uV/m measured at 3 m, see 47 C.F.R. § 15.241), some companies also manufacture ECG monitors that operate on the offset (or "splinter") channels in the 450-470 MHz band in the Business Radio Service. See 47 C.F.R. §§ 90.75, 90.217, 90.267. It should be noted that on December 14, 1994, the Critical Care Telemetry Group, of which SpaceLabs is a member, filed a Petition for Rulemaking seeking to increase the Part 15 power levels permitted for telemetry operations to the same levels employed by the Part 90 telemetry systems, i.e., up to 5 mW.

heart muscle. Irregular heart beats or other cardiac problems are identified by observing distortions in the electrical current represented by the ECG. To ensure accuracy, and to aid in identifying potential cardiac problems before they become acute, it is essential that the telemetry system provides a continuous, real-time data stream that must be absolutely error-free.[2/]

In a wireless ECG monitoring system, a small, portable unit (weighing approximately 7 oz.) is carried by the patient in a holster-style arrangement. The portable unit collects the data gathered by electrodes attached to the patient's skin and transmits them to an array of receiving antennas located in the ceiling of the corridors and other common areas of the hospital that are accessible to the patient. The signal is then carried via wire to a central point for processing and viewing, generally at a nurse's station.

Wireless ECG monitors provide both the hospital and the patient with vastly increased flexibility. Except for circumstances in which the patient is nonambulatory (e.g., in

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2/ The latest generation of portable ECG monitors, using state-of-the-art digital technology, requires a bandwidth of approximately 12.5 kHz (including guardbands) in order to provide two simultaneous "views" of the heart. Portability, power and cost considerations greatly reduce the flexibility that might otherwise be available to ECG system manufacturers. The higher power levels require larger, heavier batteries (or shorter battery life), decrease frequency reuse capabilities and, in extreme cases, may pose a threat to patient health and/or to the operation of other electronic equipment frequently encountered in the hospital environment. In general (depending on variables such as building construction and terrain shielding), frequencies presently may be successfully reused at less than 5,000 foot separations, which is a significant consideration in large urban medical centers.

intensive care), it is logistically easier, and far more cost-effective, to employ portable units. More importantly, the portable units permit ambulatory patients a great deal of freedom of movement, an aspect of the recovery process that has become increasingly important in the judgment of the medical profession.

As noted above, biomedical telemetry has fairly rigid operational requirements. Communication must be (1) instantaneous, (2) continuous, and (3) free from any interference that might cause a data error. Because of considerations relating to patient safety and battery life, transmissions must be kept to relatively low powers.

B. Current Part 90 Operations.

The soon-to-be-replaced Part 90 regulatory scheme permits: (1) any type of telemetry operations on most of the 450-470 MHz offset channels; and (2) solely biomedical telemetry in hospitals or similar medical facilities on certain offset channels in the 460 and 465 MHz bands. See 47 C.F.R. §§ 90.75, 90.267.[3/] These devices are not required to be separately licensed, so long as the hospital or other medical facility in

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3/ SpaceLabs is still assessing the impact of the new Part 90 regulatory scheme recently adopted by the Commission in the "Refarming" rulemaking, PR Docket No. 92-235, see Replacement of Part 90 by Part 88 to Revise the Private Land Mobile Radio Services and Modify the Policies Governing Them, FCC 95-255, released June 23, 1995, with regard to the number of channels that will be available in the future for low-power biomedical telemetry. While the bandwidth reductions mandated by that decision appear to increase the number of available offset channels by a significant amount (at least over time), the reality of adjacent and co-channel usage patterns may, in practical terms, substantially reduce the intended benefits of "refarming," at least insofar as low-power telemetry is concerned.

question is licensed by the FCC for other radio operations. See Licensing of Low-Power Medical Devices in the 450-470 MHz Band, 7 F.C.C. Rcd 5464 (1992) ("Blanket License Order").

The main problem that historically has confronted biomedical telemetry operations is susceptibility to interference, which stems primarily from: (1) its very low operating power; (2) the limited number of channels available in any given locale, particularly in major urban areas where high-power mobile use generally is extensive; and (3) its secondary status vis-à-vis those high-powered systems.

At present, there are approximately 280 splinter channels available for biomedical telemetry.[4/] Because of interference, many of those 280 channels may be unavailable in a particular locale, depending on the nature of co-channel and adjacent channel operations.[5/] In many major medical centers, upwards of 250 telemetry channels may be in operation at any given time, thereby essentially exhausting the available supply in the 450-470 MHz band. If one or more channels are receiving interference from an outside source, there simply may not be an alternative channel available to which to move.[6/]

4/ But see n.3 supra.

5/ Indeed, seemingly viable splinter channels sometimes turn out to suffer from periods (however brief) of totally debilitating interference, due to the random meanderings of an adjacent channel (or co-channel) licensee's high-powered mobile units. This sort of problem arises without warning, and can trigger a hospital staff response to a perceived (but nonexistent) life-threatening emergency.

6/ For reasons of cost, and to ensure proper operation, portable ECG monitors are not frequency-agile; each is tuned

(continued...)

C. Next-Generation Telemetry Requirements.

The above-described difficulties are aggravated by the growing demands of the medical profession. First, the use of wireless telemetry is increasing rapidly, particularly given the medical and financial benefits of expedited recovery periods. Wireless ECG monitors make a substantial contribution toward achieving both of those goals, and SpaceLabs' long-term plans envision that, within the decade, it will not be uncommon for a major medical center to simultaneously monitor upwards of 500 patients using wireless telemetry systems.

Second, the medical profession increasingly is demanding additional patient data from portable systems. Upcoming generations of monitors most likely will provide three views of the heart (instead of the current two), plus information on other patient parameters such as blood pressure, blood gas, and respiration. Each parameter will require a separate channel to support that new data stream.

III. THE IMPACT OF ESSENTIALLY UNREGULATED BOOSTERS ON LOW POWER MEDICAL TELEMETRY SYSTEMS

As noted in the NPRM, under Section 90.75(c)(25) of the Commission's Rules,[7] signal boosters presently may be used in the 450-470 MHz band "only on ten Business Radio Service

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[6] (...continued)
to a specific channel. Thus, moving to a new frequency to escape interference is not just a matter of flipping a switch or turning a dial. Changing frequencies requires that the first monitor be disconnected from the patient and a new one installed.

[7] 47 C.F.R. § 90.75(c)(25).

frequency pairs . . . for communications relating to the servicing and supplying of aircraft at certain specified airports." Id. at ¶ 4 (footnote omitted). This use of boosters has never been of particular concern to the medical community, because hospitals generally are located a considerable distance from airports. The NPRM proposes to permit the use of both narrowband (Class A) and broadband (Class B) boosters by essentially all Part 90 licensees throughout, inter alia, the 450-470 MHz band, operating at up to 500 mW, without any additional licensing, notification or coordination requirements. See NPRM at ¶¶ 8, 12.

SpaceLabs notes that the NPRM proposes that a licensee who employs a booster will "be responsible for eliminating harmful interference that the signal booster may cause to other licensees, and for ensuring that the basic authorized coverage area [of the licensed station] is not expanded." Id. at ¶ 6. The NPRM goes on to state, however, that "[r]eception of co-channel transmissions on shared frequencies in the same geographic area will not be considered as interference." Id. at n.8. Low-power biomedical telemetry systems must receive some protection from co-channel and adjacent channel boosters, regardless of the "secondary" nature of the telemetry systems.

Telemetry users go to great lengths to attempt to avoid primary operations because of the susceptibility of these systems to interference from high-power adjacent and co-channel sources. The specific channels selected for a particular hospital are chosen based not only on the basis of a review of the relevant

database, but also as the result of on-site monitoring. A new booster -- installed without any warning -- could cause the affected hospital to incur substantial costs in re-channeling its system. More importantly, it could directly threaten patient lives.[8/] Healthcare providers and their patients must be protected against such an eventuality.[9/]

The most effective procedure for avoiding (or at least minimizing) these problems would appear to be to require licensees planning to install a booster in the 450-470 MHz band to give all area hospitals and similar healthcare facilities sixty days notice prior to the initiation of operations.[10/] This would afford hospitals an opportunity to assess the nature and extent of the potential threat and, if need be, prepare a response to the licensee or, if the parties are unable to resolve the matter, to raise it with the Commission. Licensees should be prohibited from operating the subject booster until the matter has been resolved either through negotiation or by a Commission decision. Rather than rely merely on a rigid primary-versus-secondary user analysis, the Commission should, in such cases, base any such decision on a public interest assessment of the

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8/ While a new booster might not expand a licensee's useable coverage area, it very well could nonetheless cause destructive interference to an ECG monitoring system located just beyond that service area.

9/ These problems potentially are compounded if the Commission also authorizes the use of booster/translators. See NPRM at ¶ 10.

10/ Given the effect of the Blanket License Order (and the exceedingly low powers at which these systems operate), it is unlikely that a prior coordination requirement (e.g., through NABER) would solve the problem.

relative merits of two incompatible uses of the spectrum in question.

CONCLUSION

As the result of the foregoing, SpaceLabs requests that the Commission craft its rules in such a manner as to minimize the impact of the operation of fill-in boosters on low-power biomedical telemetry systems operating in the 450-470 MHz band.

Respectfully submitted,

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